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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/524,454      | 03/10/2000  | Kristian Berg        | 697.013US1          | 5804             |

21186 7590 10/24/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/524,454             | BERG ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | G. R. Ewoldt, Ph.D.    | 1644                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### DETAILED ACTION

1. Claims 1-11 are pending and being acted upon.
2. Applicant's new drawings, filed 8/19/03, have been found acceptable by the Examiner.
3. In view of Applicant's amendment, response, and 1.132 declaration of P.K. Selbo, filed 8/19/03, the previous objection to the specification, and the rejection under the second paragraph of 35 U.S.C. 112 have been withdrawn.
4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of inducing an *in vitro* T cell <sup>51</sup>chromium release response comprising culturing melanoma cells with a MART-1 peptide in 10ug/ml AlPcS<sub>2a</sub>, followed by exposure to 1.35 mW/cm<sup>2</sup> of light generated by Philips TL 20W/09 bulb filtered through a Cinemoid 35 filter, followed by culture with primed MART-1-specific cytotoxic T cells,

does not reasonably provide enablement for:

a method of expressing a molecule on a cell comprising photochemical internalization wherein the molecule is sufficient to generate an immune response, for the reasons of record as set forth in the paper mailed 2/10/03.

Applicant's arguments, filed 8/19/03, have been fully considered but they are not persuasive. Applicant argues, "To be enabling, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."

For this reason alone it is clear that the instant claims are not enabled. The specification provides just a single, uncontrolled, example relevant to the invention of the instant claims. Whereas the claims encompass *in vitro* and *in vivo* methods that would result in the generation of an immune response, said response further requiring MHC Class I presentation, the specification discloses only that FM3 melanoma

cells can be killed *in vitro* by the addition of a highly toxic substance ( $\text{AlPcS}_{2a}$ ). Said disclosure cannot be considered to be commensurate with the scope with the methods of the instant claims. Also note that in the 1.132 declaration of Inventor Hogset, filed 11/21/02, the claimed invention is disclosed as being "principally dependent" on factors not considered in the specification, i.e., "the amount of toxic substances generated by the photosensitizing compounds on exposure to light and the presence and toxicity of molecules which are internalized during this process". Thus, it remains the Examiner's position that the instant specification is not enabling for the methods of the instant claims.

Applicant argues that newly provided reference Mukherjee et al. and Okano & Purtilo "indicate that this test [ $^{51}\text{Cr}$  release] is an art-accepted test for surface presentation".

It is the Examiner's position that the methods of Mukherjee et al. and Okano & Purtilo are not the methods of the instant claims, in particular, the cells in the references were not also loaded with the toxin  $\text{AlPcS}_{2a}$ .

Applicant again asserts that "Example 2 demonstrates a presentation mechanism of expression on the surface of the cell by MHC class I molecules and thus shows that PCI connects to this particular presentation system."

Applicant's assertion is simply not factual; Example 2 demonstrates nothing because the experiment described therein includes no appropriate controls demonstrating that the cells are not simply killed by the introduction of toxin  $\text{AlPcS}_{2a}$ , antigen, etc.

Applicant argues that additional newly provided references, W096/07432 and Selbo et al., demonstrate that PCI works in a variety of cell types.

Applicant is advised that it is the specification, as stipulated by Applicant, not references provided post-filing, that enable a claimed invention. Additionally, whether or not PCI can be made to function in other cell types than that disclosed by the specification, the instant specification fails to address factors, such as toxin (photosensitizer or antigen), time, light wavelength, light intensity, etc., disclosed by Inventor Hogset as being critical.

Applicant is advised that an argument that all of the parameters required for the function of the claimed invention are taught by the prior art, in particular WO96/07432, or are routine, would seem to indicate that a rejection based on anticipation or obviousness would be required.

Applicant argues "the Examiner contends that one is not taught how to select a non-toxic versus toxic molecule for transfer. The present invention is not concerned with the selection of molecules for vaccination, merely how best to present such molecules. As such, any molecules suitable for vaccination can be used in the invention, and the skilled person does not need to be taught this or be taught how to make an appropriate selection."

Applicant is advised that it is not the Examiner's "contention", but rather the Inventor's teaching, as set forth in the declaration filed 11/21/02. Applicant cannot credibly argue that a factor which the Inventor describes as "principally dependent" need not now be considered.

6. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in the paper mailed 2/10/03.

Applicant's arguments, filed 8/19/03, have been fully considered but they are not persuasive. Applicant argues, that WO96/07432 adequately describes photochemical internalization as recited in the claims.

Applicant is advised that the invention of the prior art is not disclosed in the specification as being the invention of the instant claims. However, Applicant is advised that a clear stipulation by Applicant that the "photochemical internalization" of the instant claims is the "photochemical internalization" of the prior art will obviate the rejection.

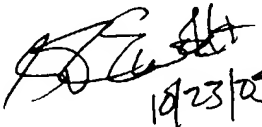
7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
October 23, 2003

  
10/23/03  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**